THE GOVERNMENT -------	SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom - Happiness ----------
No. 36/2016/ND-CP	*Hanoi, May 15th, 2016*

DECREE

ON MEDICAL EQUIPMENT MANAGEMENT

Pursuant to the Law on Government organization dated December 25, 2001;

Pursuant to the Law on Investment dated November 26, 2014;

At the request of the Minister of Health;

The Government hereby promulgates the Decree on medical equipment management.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Decree provides for the management of medical equipment, including the classification of medical equipment; the manufacture, free sale of medical equipment and provision of services related to medical equipment; information and label of medical equipment and the management and use of medical equipment at medical facility.

Article 2. Interpretation of terms

1. ”Medical equipment” includes equipment, tools, materials for implanting activities, reagents and in vitro calibration solutions, software which are used seperately or in association with each other according to the instruction of their owners for human use for one or more of the following purposes:

a) To diagnose, prevent, supervise, treat and eliminate the illness or to make up for pains;

b) To examine, replace, adjust or assist surgery activities or phisiology processes;

c) To support or sustain life;

d) To control the conception;

dd) To sterilize medical equipment, including chemicals used in testing;

e) To serve the specialized transport or use for healthcare activities;

g) Provide information serving the diagnosis, supervision and treatment through the examination of samples taken from human body.

2. “In vitro diagnosis medical device” includes reagents, calibration solutions, control materials, tools, machinery, devices and systems which are used separately or together according to the instruction of their owners to serve the examination of samples taken from human body.

3. “Fittings” are products which are decided by the owner of the medical equipment to be used for a specific purpose together with a specific medical equipment to facilitate or assist such equipment to be used for its intended use.

4. The owner of the medical equipment is an organization or an individual that:

a) Provide medical equipment using its/his/her name or any label, design, trade name or other name or code within the possession of such individual/organization;

b) Take responsibility for the design, production, assembly, processing, labelling, packaging or the repair of medical equipment or the determination of the use of such medical equipment.

Article 3. Rules on management of medical equipment

1. Assure the quality and safety of medical equipment and assure the effective use thereof.

2. Promptly provide sufficient and accurate information about specifications and uses of medical equipment and possible risks thereby to the users.

3. Ensure the traceability of the origin of the medical equipment.

4. The management of medical equipment must be based on the classification according to levels of risks and the respective national standards and National technical regulations which are issued or recognized by competent authorities or published and applied by organizations/individuals according to laws.

5. Medical equipment being measurement instruments or radiological equipment must be managed according to laws on measuring and laws on atomic energy and the provisions of this Decree.

Chemicals and preparations which are used only for sterilizing medical equipment shall be managed according to regulations in this Decree. Chemicals and preparations which are used not only for sterilizing medical equipment but also for other purposes shall be managed according to laws pertaining to chemicals and/or preparations killing insects and bacteria for domestic and medical use.

Chapter II

CLASSIFICATION OF MEDICAL EQUIPMENT

Article 4. Medical equipment's types

Medical equipment shall be classified into 2 groups which are divided into 4 types depending on the possible levels of risks related to the design and production of such medical equipment:

1. Group 1 comprises Type A medical equipment which is medical equipment with low level of risks.

2. Group 2 comprises Type B, C and D medical equipment, where:

a) Type B medical equipment is medical equipment with lower average level of risks;

b) Type C medical equipment is medical equipment with upper average level of risks;

c) Medical equipment of Type B is medical equipment with high level of risks.

Article 5. Rules on classification of medical equipment

1. The classification of medical equipment must be based on the classification of levels of risks.

2. If medical equipment can be classified into multiple levels of risks, its highest level of risks shall prevail.

3. If the medical equipment is intended to be used together with other medical equipment, such equipment shall be classified separately.

4. If the medical equipment is intended to be used together with other medical equipment or the medical equipment has multiple uses, the classification must be based on its most important use.

5. The Minister of Health shall be responsible for detailing the classification of medical equipment according to international treaties on classification of medical equipment by Association of Southeast Asian Nations to which Vietnam is a signatory.

Article 6. Conduct of classification of medical equipment

1. The classification of medical equipment must be conducted by an organization satisfying conditions specified in Article 7 of this Decree.

2. The organization conducting the classification of medical equipment must take legal responsibility for the classification of such medical equipment.

3. If there is difference in the classification of medical equipment, such classification shall be decided by the Ministry of Health.

Article 7. Requirements to be satisfied by organizations conducting classification of medical equipment

1. Any organization must satisfy the following requirements to conduct the classification of medical equipment

a) Legally established as prescribed by laws;

b) Having qualified medical equipment-classifying employees according to clause 2 of this Article.

2. Conditions of medical equipment-classifying employees:

a) Having at least a bachelor's degree in technology or medicine/pharmacy;

b) Having at least 24 months' experience of working in the field of medical equipment technologies at hospitals, medical facilities having beds, training institutions specified in medical equipment, facilities researching medical equipment, establishments producing medical equipment, organizations conducting the classification of medical equipment, agencies managing medical equipment (hereinafter referred to as "medical equipment facilities");

c) Having been tested and recognized by a training institution as capable of classifying medical equipment according to the training program issued by the Ministry of Health.

3. Such organizations shall conduct the classification of medical equipment only when it has obtained the receipt note for the declaration of eligibility to classify medical equipment from the Ministry of Health according to provisions of point b clause 1 Article 9 of this Decree.

Article 8. Declaration of eligibility to classify medical equipment

1. A declaration of elibility to classify medical equipment shall consist of:

a) A written document announcing the eligibility to classify medical equipment using the form No. 01 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree; accompanied by a written certificate of working time using the form in Annex III enclosed with this Decree and qualifications of each employee conducting the classification of medical equipment.

2. Requirements for documents in the declaration:

a) Original copies or certified true copies of the certificates of working time;

b) Certified true copies of qualifications of employees conducting the classification of medical equipment.

Article 9. Procedures for declaring eligibility to classify medical equipment

1. Procedures for declaring the eligibility to classify medical equipment:

a) Before classifying medical equipment, the organization conducting the classification of medical equipment shall send the declaration of eligibility to classify medical equipment specified in clause 1 Article 8 of this Decree to the Ministry of Health;

b) If the declaration is satisfactory, the Ministry of Health shall issue the organization conducting the classification with the receipt note using the form No. 01 specified in Annex IV enclosed herewith;

c) Within 03 working days from the date written on the receipt note, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the organization conducting the classification of medical equipment and the declaration of eligibility to classify medical equipment.

2. If there is any modification in the declaration during its operation, the organization conducting the classification of medical equipment shall re-conduct the procedures for declaration of eligibility to classify medical equipment.

Article 10. Recognition of classification of medical equipment

1. Medical equipment are not required to be reclassified in Vietnam if it has been classified by a competent regulatory body of a country recognized by Vietnam on the basis of international treaties or international arrangements to which Vietnam is a party or of a country which adopts a medical equipment classification system similar to that adopted by Vietnam.

2. The Minister of Health shall publish the list of countries whose medical equipment classifications have been recognized by Vietnam.

Chapter III

PRODUCTION OF MEDICAL EQUIPMENT

Article 11. Investment incentives for the production of medical equipment

1. Reduction or exemption from rents for State owned land:

a) Any investor having a project of producing Type B medical equipment that leases state-owned land shall be eligible for the rental rate prescribed by People's Committees of provinces/central-affiliated cities and shall be eligible for exemption from land rents according to laws;

b) Any investor having a project of producing Type C or D medical equipment shall be eligible for exemption from land rents from the day on which the project is launched;

c) Any investor having a project of producing medical equipment shall be eligible for exemption from rents for land used for the construction of accommodations for employees or for planting public trees.

2. Apart from investment incentives specified in clause 1 of this Article, the project of producing medical equipment shall be eligible for other investment incentives as prescribed by laws on investment and science and technology.

Article 12. Requirements for employees of producers of medical equipment

1. The professionals must:

a) Have qualifications specified in medical equipment technology of college level or higher or having qualifications specified in technique or medicine of university level or higher;

b) Have at least 24 months experience of working in the field of technique of medical equipment at a medical equipment-providing facility for at least 24 months;

c) Be a full-time worker at the producer's factory. The assignment and appointment of professionals producershall be made in writing.

2. producerOther employees must satisfy requirements for producing medical equipment producermanufactured.

Article 13. Requirements for infrastructures, equipment and quality control of producers of medical equipment

1. Having conditions of location, area and factory in conformity with the medical equipment that such producer produces.

2. Having equipment and procedures of production and quality inspection in conformity with the medical equipment that such producer produces. In case there is no equipment for quality inspection, a contract with an establishment capable of conducting quality inspection for the medical equipment shall be concluded.

3. Having storage facilities at least conformable to the following conditions:

a) Having area in accordance with the type and the quantity of the medical equipment to be stored;

b) Being airy, dry, clean, separate from sources of pollution;

c) Satisfying other storing requirements applicable to medical equipment according to the instruction.

4. Having vehicles for delivering medical equipment from producing establishments in accordance with the medical equipment.

5. Applying the quality control system prescribed in clause 1 Article 68 of this Decree.

6. If the establishment does not have storage facilities and vehicles for transporting medical equipment, a contract with an establishment satisfying requirements for storage facilities and transport of medical equipment as prescribed in clauses 3 and 4 of this Article shall be concluded.

Article 14. Declaration of eligibility to produce medical equipment

A declaration of eligibility to produce medical equipment shall consist of the following documents:

1. A declaration of eligibility to produce medical equipment using the form No. 02 specified in Annex I enclosed with this Decree.

2. A list of employees using the form specified in Annex II enclosed with this Decree.

3. A document on assignment/appointment of professionals of the producing establishment, enclosed with the certificates of working time using the form in Annex III enclosed with this Decree and qualifications of the professionals.

4. A certificate of conformity with quality control standards.

In case of unavailability of the certificate of conformity with quality control standards, documents proving facilities satisfying requirements specified in clauses 1, 2, 3 and 4 Article 13 of this Decree are required.

In case the establishment fails to conduct the product quality inspection itself, or in case the establishment does not have storage facilities or transport vehicle and sign a contract with another establishment for quality inspection, storage and transport, documents proving that such contracting establishment is capable of conducting quality inspection, storing and transporting medical equipment produced by the producing establishment must be enclosed.

Article 15. Requirements for declaration of eligibility to produce medical equipment

1. The declaration of eligibility to produce medical equipment shall be made in 1 copy, where:

a) Documents shall be readable and arranged according to the order provided for in Article 14 of this Decree; there shall be separators between different parts, there shall be cover pages and the table of contents;

b) Documents must be made in either English or Vietnamese.

2. Requirements for documents in the declaration of eligibility to produce medical equipment:

a) An original copy or a certified true copy of the written assignment/appointment or qualifications of professionals of the producing establishment;

b) The original copies or the certified true copies of documents proving that the establishment satisfying requirements specified in clauses 1, 2, 3 and 4 Article 13 of this Decree;

c) An original copy or a certified true copy or a copy certified by the applicant establishment of the Certificate of conformity with quality control standards.

Article 16. Procedures for making declaration of eligibility to produce medical equipment

1. The establishment shall carry out the production of medical equipment only when it has obtained the receipt note prescribed in point b clause 2 of this Article.

2. Procedures for making declaration of eligibility to produce medical equipment:

a) Before producing medical equipment, heads of medical equipment producing establishments shall send a declaration of eligibility to produce medical equipment specified in Article 14 of this Decree to the Department of Health of the area where the producing establishment is headquartered;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the receipt note using the form No. 02 in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the receipt note, the Department of Health shall publish the following information on its web portal: name of the establishment; the professionals in charge; medical equipment produced by the establishment; contact address and phone number and the declaration of eligibility to produce medical equipment, except for the producing procedures and the quality inspection prodedures.

3. During its operation, if there is any change related to the accepted declaration, the producing establishment shall re-conduct the procedures for declaration of eligibility to produce medical equipment.

4. If the producing establishment has its producing site relocated to another province, is must notify the Department of Health where it has make the declaration of eligibility to produce medical equipment within 10 working days from the date of relocation.

Within 03 working days from the day on which the notification of the relocation of producing site is received, the Department of Health receiving the declaration of eligibility to produce medical equipment shall terminate the publication of information relevant to such establishment.

Chapter IV

FREE SALE OF MEDICAL EQUIPMENT

Section 1. REQUIREMENTS FOR FREE SALE, FREE-SALE REGISTRATION NUMBER AND REQUIREMENTS FOR ORGANIZATION DECLARING APPLICABLE STANDARDS OR CONDUCTING REGISTRATION

Article 17. Requirements for free sale of medical equipment

1. Any medical equipment to be freely sold must satisfy the following requirements:

a) Having effective free-sale registration number or having obtained permission for import according to provisions of this Decree;

b) Having label or supplementary label containing sufficiently information specified in Article 54 of this Decree;

c) Having technical documents serving the repair and maintenance of medical equipment, excluding disposable medical equipment prescribed by its owner;

d) Having Vietnamese instruction of how to use the medical equipment;

dd) Having information about warranty establishments, conditions and duration, unless the equipment is disposable as decided by its owner.

2. The information specified in points c, d and dd clause 1 of this Article which is not enclosed with the equipment must be provided in form of electronic information; guidelines for accessing to such information must be clearly stated on the label of the medical equipment.

Article 18. Conditions for declaring applicable standards of application or issuance of certificate of free-sale registration for medical equipment

1. Conditions for declaring the applicable standards or the issuing the certificate of free-sale registration for medical equipment

a) Such equipment shall be manufactured at the producing establishment which has declared its eligibility to produce domestically produced medical equipment;

b) Such equipment shall be manufactured at an establishment which has been issued with the Certificate of conformity with quality control standards and permitted to be freely sold in any country in the world, applicable to imported medical equipment;

c) Such equipment shall be conformable to National technical regulation or the standard that the producer has declared to be applied.

2. The re-conduct of the procedures for declaring the applicable standards or conducting registration of free sale shall not be applicable to:

a) Medical equipment specified in clause 1 Article 34 of this Decree;

b) Medical equipment that is recalled according to regulations in clauses 1 and 3 Article 35 of this Decree.

3. The declaration of applicable standard or the application for registration of free sale of medical equipment of any of cases specified in clauses 2 and 8 Article 35 of this Decree shall not be accepted for 12 months from the day on which the decision to revoke the free-sale registration number is issued.

Article 19. Medical equipment exempt from declaring applicable standards and free-sale registration

1. Medical equipment that is used solely for researching, testing or repairing medical equipment or guiding the use thereof.

2. Medical equipment imported into Vietnam for assisting purpose or for displaying at a fair, exhibition or for product introduction or as a gift.

3. Medical equipment produced in Vietnam solely for export or for displaying at an overseas fair or exhibition.

Article 20. Free-sale registration number of medical equipment

1. Free-sale registration number of medical equipment means:

a) The number of the receipt note of the declaration of applicable standard, applicable to Type A medical equipment, using the form No. 03 provided in Annex IV enclosed with this Decree;

b) The number of the certificate of registration of free sale, applicable to type B, C or D medical equipment, using the form No. 09 provided in Annex IV enclosed with this Decree.

2. The registration number of free sale of medical equipment may be issued to one or a group of medical equipment type.

3. The holder of the free-sale registration number is the organization declaring the applicable standards, applicable to type A medical equipment, or the organization obtaining the free-sale registration number, applicable to type B, C or D medical equipment.

4. Effect of the free-sale registration number:

a) The registration number of free sale of type A medical equipment shall be permanently effective;

b) The registration number of free sale of type B, C or D medical equipment shall be effective for 05 years from the date of issue. In case where the effect of the registration number is extended, the registration number shall be retained.

Article 21. Requirements for organizations declaring applicable standards or applying for registration of free sale of medical equipment

1. The following organizations are allowed to declare the applicable standards or applying for the registration of free sale of medical equipment:

a) Vietnamese enterprises, cooperatives or business households that are in possession of medical equipment;

b) Vietnamese enterprises, cooperatives or business households trading medical equipment that are authorized by medical equipment's owners to follow the registration procedures;

c) Standing representative offices in Vietnam of foreign traders who are the owners of the medical equipment or who are authorized by the owners of the medical equipment.

2. Any organization declaring the applicable standard or carrying out registration of free sale of medical equipment must have warranty establishments in Vietnam or sign a contract with an organization capable of providing warranty services on medical equipment which is registered by its name, except for disposable medical equipment as prescribed by the owners of such medical equipment.

If the organization declaring the applicable standard or conducting the registation of free sale of medical equipment is of those specified in point c clause 1 of this Article, the owners of the medical equipment sign a contract with an organization capable of providing warranty services on medical equipment which is declared by its name, except for disposable medical equipment as prescribed by the owners of such medical equipment.

The warranty establishment shall be certified by the owner of the medical equipment to be capable of providing warranty on products which are registered by such organization.

Section 2. PUBLICATION OF APPLICABLE STANDARDS OF TYPE A MEDICAL EQUIPMENT

Article 22. Declaration of applicable standard

The declaration of applicable standard for type A medical equipment shall consist of:

1. A declaration of the applicable standard of type A medical equipment using the form No. 03 provided in Annex I enclosed with this Decree.

2. A classification table using the form in Annex V enclosed with this Decree.

3. A receipt note of the declaration of eligibility to produce medical equipment, applicable to domestically produced equipment, or the Certificate of conformity with quality control standards which is effective by the time of declaration, applicable to imported equipment.

4. The power of attorney by the owner of the medical equipment for the organization declaring the applicable standard using the form in Annex VI enclosed with this Decree which is effective by the time of declaration, except for cases specified in point a clause 1 Article 21 of this Decree.

5. The certificate of eligibility to provide warranty issued by the owner of the medical equipment using the form provided in Annex II enclosed with this Decree, excluding disposable medical equipment prescribed by its owner.

6. Documents that give brief description of medical equipment technology using the form No. 01 in Annex VIII enclosed with this Decree.

7. The standard which the owner of the medical equipment declares to apply or the Certificate of conformity.

8. Written instruction for the medical equipment.

9. The label of the medical equipment which is intended to be used when it is sold in Vietnam.

Article 23. Requirements for declaration of applicable standards

1. The declaration of applicable standard shall be made in 01 dossier.

2. Requirements for a number of documents in the declaration of applicable standard:

a) Regarding the receipt note of the declaration of eligibility to produce medical equipment: a copy which is certified by the organization declaring the applicable standard is required.

b) Regarding the Certificate of conformity with quality control standard: an original copy or a certified true copy or a copy certified by the establishment declaring the applicable standard is required;

If the copy certified by the organization declaring the applicable standard is used, at the time of submission of the declaration, the original copy shall be presented for comparison or data sources shall be provided so that the receiving body checks the validity of such documents;

Any Certificate of conformity with quality control standard which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

c) Regarding the power of attorney of the owner of medical equipment and the Certificate of eligibility to provide warranty:

- Regarding domestically produced medical equipment: an original copy of a certified true copy is required;

- Regarding imported medical equipment: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

d) Regarding the Certificate of conformity or the standard declared by the owner of the medical equipment: a copy certified by the organizartion declaring the applicable standard is required.

Any Standard which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws;

dd) Regarding the instructions for the medical equipment: a Vietnamese copy certified by the organization declaring the applicable standard is required;

e) Regarding the label model: a copy which is certified by the organization declaring the applicable standard is required. The label model must satisfy requirements specified in Article 54 of this Decree.

Article 24. Procedures for declaring applicable standard

1. Type A medical equipment shall be freely sold only when the receipt note for the declaration of applicable standard has been issued by the Department of Health as prescribed in point b clause 2 of this Article.

2. Procedures for declaring applicable standard:

a) Before releasing type A medical equipment, the establishment in charge of selling medical equipment shall send the declaration of applicable standard specified in Article 22 of this Decree to the Department of Health of the area where such establishment is headquartered;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the Receipt note using the form No. 03 in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the receipt note, the Ministry of Health shall publish the following information on its web portal: name, classification, producer, country of origin of medical equipment; registration number of free sale of the medical equipment; name, address of the owner of the medical equipment; name, address of the holder of the registration number; name, address of the establishment providing warranty services on medical equipment and the declaration of applicable standard for medical equipment.

3. If the owner of the medical equipment or the producer of the medical equipment is changed, the holder of the free-sale registration number shall re-conduct the procedures for declaration of the applicable standard according to provisions of this Decree.

Section 3. REGISTRATION OF FREE SALE OF TYPE B, C OR D MEDICAL EQUIPMENT

Article 25. Forms of registration fo free sale

1. A new registration number of free sale shall be issued to the following medical equipment:

a) Medical equipment which applies for free-sale registration number for the first time;

b) Medical equipment which has been issued with the free-sale registration number and has been modified in type or producing materials (that affects its functions, applicable to in vitro diagnosis device and disposable medical equipment);

c) Medical equipment which has been issued with free-sale registration number and its owner fails to apply for extension of its free-sale registration number within the time specified in clause 3 Article 27 of this Decree.

2. The free-sale registration number shall be re-issued if the Certificate of free sale is lost or damaged.

3. The time limit of the free-sale registration number shall be extended of the registration number nearly expires as prescribed in clause 3 Article 27 of this Decree.

Article 26. Application for new free-sale registration number

1. An application for the registration number of free sale of medical equipment for which there is no applicable National technical regulation:

a) A written application form for a new free-sale registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) A classification table using the form in Annex V enclosed with this Decree;

c) The certificate of conformity with quality control standards which is effective at the time of application, unless the medical equipment has been issued with the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, Therapeutic Goods Administration (TGA) of Australia, Food and Drug Administration (FDA) of America;

d) The power of attorney by the owner of the medical equipment for the establishment conducting the free-sale registration using the form in Annex VI enclosed with this Decree which is effective by the time of application, except for cases specified in point a clause 1 Article 21 of this Decree;

dd) The certificate of eligibility to provide warranty issued by the owner of the medical equipment using the form provided in Annex II enclosed with this Decree, excluding disposable medical equipment prescribed by its owner;

e) The Certificate of free sale which is effective at the time of application, applicable to imported medical equipment;

g) Vietnamese documents that give brief description of medical equipment using the form No. 01 in Annex VIII enclosed with this Decree;

h) A catalogue describing functions and specifications of medical equipment; technical information on reagents, calibration solutions, in vitro control materials using the form No. 02 provided in Annex VIII enclosed with this Decree;

i) Written instruction for the medical equipment;

k) Regarding type C or D medical equipment which is used by putting into human body: the summary of clinically testing data using the form in Annex IX enclosed with this Decree together with the clinically testing reseach results are required, unless:

- Medical equipment is manufactured or processed in Vietnam solely for export and the importing country does not request clinical testing;

- Such medical equipment has been freely sold and obtained the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, TGA of Australia, FDA of America;

- Other cases specified by the Minister of Health.

l) Type C or D medical equipment for in vitro diagnosis must have the certificate of inspection as prescribed by the Minister of Health, unless the medical equipment has been issued with the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, canada, TGA of Australia, FDA of America;

m) The label of the medical equipment which is intended to be used when such medical equipment is freely sold in Vietnam.

2. Regarding the application for the registration number of free sale of medical equipment with applicable National technical regulations:

a) A written application form for a new free-sale registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) The certificate of conformity;

c) Papers specified in points b, c, d, dd, e, g, h, i and m clause 1 of this Article.

3. Regarding the application for a new registration number of free sale of medical equipment being measurement instruments subject to obtaining the approval of the model according to laws on measuring:

a) A written application form for a new free-sale registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) The decision to approve the model;

c) Papers specified in points b, c, d, dd, e, g, h, i and m clause 1 of this Article.

4. Regarding the application for a new registration number of free sale of medical equipment being measurement instruments which is not required to obtain the approval for the model as prescribed in laws on measuring, regulations in clause 1 of this Article shall be complied with.

Article 27. Application for reissuance/extension of free-sale registration number

1. The application for reissuance of the free-sale registration number which is lost or damaged shall include an application form using the form No. 05 provided in Annex I enclosed with this Decree.

2. An application for extension of the free-sale registration number shall consist of:

a) A written application form for extension of free-sale registration number using the form No. 06 provided in Annex I enclosed with this Decree;

b) A copy of the obtained certificate of free sale;

c) The certificate of conformity with quality control standards which is effective at the time of application, unless the medical equipment has been issued with the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, Therapeutic Goods Administration (TGA) of Australia, Food and Drug Administration (FDA) of America;

d) The power of attorney by the owner of the medical equipment for the establishment conducting the registration of free sale using the form in Annex VI enclosed with this Decree, except for cases specified in point a clause 1 Article 21 of this Decree;

dd) The Certificate of free sale which is effective at the time of application, applicable to imported medical equipment;

e) The income statement for the period when the free-sale registration number is obtained using the form in Annex X enclosed with this Decree.

3. Time limit for applying for extension of the free-sale registration number shall be at least 60 days before it expires.

Article 28. Requirements for application for new issuance/extension of free-sale registration number

1. An application for new issuance or extension of the registration number of free sale of medical equipment shall be made in 01 dossier and documents in such dossier shall be readable and shall be arranged according to the order specified in Article 26 of this Decree, applicable to applications for new inssuance of the free-sale registration number, or in clause 2 Article 27 of this Decree, applicable to applications for extension of the free-sale registration number; there shall be separators between different parts, there shall be cover pages and the table of contents.

2. Requirements for a number kinds of papers in the application for new issuance/extension of free-sale registration number:

a) Regarding the Certificate of conformity with quality control standards: the original copy or a certified true copy or a copy certified by the applicant establishment is required.

In case of including the copy certified by the applicant establishment, the original copy shall be presented for comparison or data sources shall be provided for checking the validity of such documents, at the time of submission of the application.

Any Certificate of conformity with quality control standard which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

b) Regarding the power of attorney of the owner of medical equipment and the Certificate of eliogibility to provide warranty:

- Regarding medical equipment manufactured in Vietnam: an original copy of a certified true copy is required;

- Regarding imported medical equipment: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

c) Regarding the Certificate of Free sale: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

Any Certificate of free sale which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

If the certificate of free sale does not specify the date of expiry, such certificate shall expire after 36 months counted from the date of issue.

d) Regarding catalogue of the medical equipment: the copy certified by the applicant is required.

Any catalogue which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws;

dd) Regarding the instructions for the medical equipment: a Vietnamese copy certified by the applicant establishment is required.

e) Regarding the certificate of inspection: the original copy or a certified true copy or a copy certified by the applicant establishment is required.

In case of including the copy certified by the applicant, the original copy shall be presented at the time of submitting the application for comparison.

g) Regarding the label model: a copy which is certified by the organization registering for free sale of medical equipment. The label model must satisfy requirements specified in Article 54 of this Decree.

Article 29. Receipt and inspection of application for registration number of free sale of medical equipment

1. Any establishment applying for the free-sale registration number shall submit the application at the Ministry of Health.

2. When receiving satisfactory application, the Ministry of Health shall issue the applicant establishment with the receipt note using the form No. 04 provided in Annex IV enclosed with this Decree.

3. In case the application is satisfactory and not any modification is required, the Minister of Health shall:

a) Regarding medical equipment for which there is no applicable National technical regulation: Conduct inspection for new issuance of the registration number within 60 days or for extension of the registration number within 30 days from the date written on the receipt note. In case of refusal to issue or grant extension of the registration number, a written response containing explanation shall be made;b) Regarding medical equipment with applicable National technical regulation: Conduct inspection for new issuance of the registration number within 15 days or for extension of the registration number within 10 days from the date written on the receipt note. In case of refusal to issue or grant extension for the registration number, a written response containing explanation shall be made;

c) The re-issuance of the free-sale registration number shall be carried out within 05 working days from the date written on the receipt note. In case of refusal to re-issue the free-sale registration number, a written response containing explanation shall be made.

4. If the application for the registration number is not satisfactory, the Ministry of Health shall send a written notification to the establishment applying for new issuance, re-issuance or extension of the registration requesting the modification, detailing documents and information subject to modification within the periods specified as follows:

a) 15 working days from the date written on the receipt note, applicable to applications for new issuance or extension of the registration;

b) 05 working days from the date written on the receipt note, applicable to applications for re-issuance of the registration.

5. After receiving the request for modification of the application for the registration number, the applicant establishment shall complete the documents according to the written notification and send them to the Ministry of Health. The date of receipt of the completed application shall be written on the receipt note.

In case where the applicant establishment has modified its application unconformably with the request, the Ministry of Health shall request the applicant establishment to continue completing the application according to regulations in clause 4 of this Article.

After 60 days from the day on which the written notification by the Ministry of Health is received, if the applicant establishment fails to complete its application, it shall re-conduct the procedures for applying for the registration number.

6. If the inspection council request the modification of the application, within 10 working days from the day on which the meeting minute of the council is made, the Ministry of Health shall send a written notification to the applicant establishment for modification of the application. The notification shall specify the information to be supplemented and the information to be adjusted.

After receiving the request for modification of the application for the free-sale registration number, the applicant establishment shall modify the documents according to the written notification and re-send the application to the Ministry of Health. The date of receipt of the completed application shall be written on the receipt note.

In case where the applicant establishment has modified its application unconformably with the request, the Ministry of Health shall request the applicant establishment to continue completing the application according to regulations in clauses 4 and 5 of this Article.

7. Within 03 working days from the day on which the free-sale registration number is issued, the Ministry of Health shall publish on its web portal the following information:

a) Name, classification, producer and country of origin of the medical equipment;

b) Registration number free sale of the medical equipment;

c) Name and address of the owner of the medical equipment;

d) Name and address of the holder of the free-sale registration number;

dd) Name and address of the warranty provider of the medical equipment;

e) The application for registration number of free sale of the medical equipment, except for information specified in points g and h clause 1 Article 26 of this Decree.

8. During the period of free sale of medical equipment, the holder of the registration number shall send a written notification to the Ministry of Helath within 10 working days from the day on which any of the following activities is conducted:

a) The address of the owner of the medical equipment or of the holder of the registration number of free sale of the medical equipment is changed;

b) Name of the holder of the free-sale registration number is changed. The holder of the registration number shall enclose with the written notification documents proving the ownership towards the medical equipment of the new owner and the label model prescribed in Article 54 of this Decree;

c) Information about name or address of the producer of the medical equipment is modified. The holder of the free-sale registration number shall enclose with the written notification of modification the following documents: the Certificate of Free sale and the Certificate of conformity with quality control standards which are effective at the time of application, unless the medical equipment has been issued with the Certificate of Free sale by the competent body

of any of the following countries and organizations: EU member countries, Japan, canada, TGA of Australia, FDA of America;

d) The packing specifications are changed, applicable to in vitro diagnosis medical devices. The holder of the free-sale registration number shall enclose with the written notification documents specified in points h and m clause 1 Article 26 of this Decree;

dd) The warranty provider is changed. The holder of the free-sale registration number shall enclose with the written notification documents specified in points dd clause 1 Article 26 of this Decree.

9. Within 03 working days from the day on which the notification by the holder of the free-sale registration number is issued, the Ministry of Health shall update the modifed information on its web portal the following information.

10. The Minister of Health shall issue regulations on the inspection of the application for registration number.

Section 4. TRACING ORIGIN AND HANDLING DEFECTIVE MEDICAL EQUIPMENT, SUSPENSION OF FREE SALE OR RECALLING OF DEFECTIVE MEDICAL EQUIPMENT AND HANDLING OF MEDICAL EQUIPMENT IN SPECIFIC CASES

Article 30. Tracing the origin of defective medical equipment

1. Regarding defective medical equipment, the holder of the free-sale registration number shall trace the origin, including:

a) Determining name, type and amount of medical equipment in the defective batch;

b) Publishing on the web portal of the owner (if any) and the web portal of the Ministry of Health, and requesting establishments producing, trading or using such medical equipment in writing to provide information on name, type and the amount of medical equipment in the defective batch, the actual amount remained in the storage and the actual amount being on market;

c) Formulating plans on measures to be taken or on the recall of defective medical equipment;

d) Report to a competent agency the plans specified in point c of this Clause.

2. The competent agency shall conduct inspection and monitor the tracing of the origin of the defective medical equipment within its management.

Article 31. Handling and recalling defective medical equipment

1. Measures to be taken for defective medical equipment:

a) Providing guidelines on remedial measures;

b) Eliminating defects of the medical equipment;

c) Replacing the defective medical equipment with the equivalent one;

d) Recalling for re-exporting or destruction.

2. Defective medical equipment shall be recalled as follows:

a) Voluntary recalling conducted by the holder of the free-sale registration number;

b) Compulsory recalling, for cases specified in Article 35 of this Decree.

3. The holder of the free-sale registration number of the defective medical equipment shall recall and take measures for defective medical equipment within a period specified by the competent agency and shall pay all the cost for the recall and handling of the defective medical equipment.

If the holder of the free-sale registration number fails to recall the defective medical equipment within the time limit specified by the competent agency, the recall shall be enforced as prescribed legislation on penalties for administrative violations.

Article 32. Procedures for suspension of sale of defective medical equipment against which a warning has been issued by owner of medical equipment

1. If the medical equipment is found to be defective and have bad effect on users' health, the holder of the free-sale registration number shall:

a) Suspend such medical equipment from free sale;

b) Send a written notification to the Ministry of Health and organizations and persons that are selling or using such medical equipment. The notification shall specify the manufacture batch, the factor causing bad effect on users' health and the statement whether such factor can be eliminated.

2. In case the defect of the medical equipment that causes bad effect on users' health can be eliminated:

a) Within 03 working days from the day on which the notification by the owner of the medical equipment is received, the Ministry of Health shall issue a decision to suspend the free sale of such medical equipment;

b) When the decision to suspend the free sale of the medical equipment has been issued, the holder of the free-sale registration number in Vietnam shall take measures to eliminate the factor that causes bad effect on users' health;

c) After completing the elimination of the factor thats cause bad effect on users' health, the holder of the free-sale registration number shall send a written report to the Ministry of Health which contains the undertaking to assure the quality of the medical equipment after the elimination or the inspection result by a laboratory which is conformable to the TCVN ISO/IEC 17025 national standard or the ISO/IEC 17025 international standard or a equivalent standard;

d) Within 20 days as from the day on which the report specified in point c of this Clause is received, the Ministry of Health shall issue a decision to terminate the suspension of the medical equipment If the Ministry of Health refuse to terminate the suspension, a written response containing explanation shall be made.

3. If the defect of the medical equipment that causes bad effect on users' health can not be eliminated, the Ministry of Health shall issue a decision to recall all the equipment of the batch of medical equipment which incurs the suspension.

4. The decision to suspend the free sale shall consist of:

a) Name of medical equipment to incur the suspensioon;

b) The number of the batch of medical equipment to incur the suspension;

c) The registration number of free sale of the medical equipment to incur the suspension;

Article 33. Procedures for suspension of free sale of defective medical equipment against which a warning has been issued by a competent

1. Within 05 working days as from the day on which the notification of the defect that causes bad effect on users' health made by a medical facility of another country where the medical equipment is sold or by World Health Organization is received, the Ministry of Health shall send a written request to the holder of the free-sale registration number for explanatory report.

2. Within 05 working days from the day on which the written response by the Ministry of Health is received, the holder of the free-sale registration number shall send a written report to the Ministry of Health.

3. Within 5 working days from the day on which the report made by the holder of the free-sale registration number of medical equipment in Vietnam is received, the Ministry of Health shall establish a scientific council for assessing the defect that causes bad effect on users' health.

4. If the medical equipment is defined to not have any factor causing bad effect on users' health, within 03 working days from the day on which the meeting minutes of the council is received, the Ministry of Health shall issue the written notification to the holder of the free-sale registration number in Vietnam.

5. If the medical equipment is defined to have defect causing bad effect on users' health, the Ministry of Health shall follow the procedures for suspension of free sale of such equipment according to regulations in clauses 2, 3 and 4 Article 32 of this Decree.

Article 34. Handling of medical equipment whose owner or whose registration number's holder terminates the production or is bankrupt or dissolved

1. If the medical equipment has been issued with the registration number but the owner of such medical equipment declares terminating the production or declares bankrupcy or dissolution, such medical equipment shall be on market for not exceeding 24 more months counted from the date of such declaration, provided that the holder of the registration number in Vietnam shall undertake to provide the warranty and maintenance as well as provide materials for replacing or serving the use of medical equipment for 08 years, unless the holder of the registration number is the standing representative office in Vietnam of the foreign trader who is the owner of such medical equipment.

2. If the medical equipment has been issued with the registration number but the holder of such medical equipment is bankrupt or dissolved, such medical equipment shall be on market for not exceeding 24 months counted from the date of such bankrupcy/dissolution, provided that the distributing establishment shall undertake to provide the warranty and maintenance as well as provide materials for replacing or serving the use of medical equipment for not more than 08 years.

3. The holder of the registration number or the distributing establishment shall send the dossier about its undertaking to the Ministry of Health within 60 days from the day on which the owner of the medical equipment or the holder of the registration number declares terminating the manufacture or declares bankrupcy or dissolution.

4. The undertaking dossier shall consist of:

a) A written undertaking to provide the warranty and maintenance and provide materials serving the use of medical equipment using the form provided in Annex XI enclosed with this Decree;

b) A list of medical equipment having registration number kept by such establishment whose owner or whose registration number's owner of the medical equipment declared terminating the manufacture or declared bankrupcy or dissolution.

5. Within 15 working days from the day on which the undertaking prescribed in clause 4 of this Article, the Ministry of Health shall make a written response on the approval or refusal of the application for continuing the free sale of medical equipment. In case of refusal, explanation shall be provided.

6. If the free sale of medical equipment specified in clauses 1 and 2 of this Article is not allowed by the Ministry of Health to be continued, the holder of the free-sale registration number or the distributing establishment shall recall all the medical equipment being on market, unless such equipment has been freely sold.

Section 5. REVOCATION OF REGISTRATION NUMBER OF FREE SALE OF MEDICAL EQUIPMENT

Article 35. Cases where registration number is revoked

1. The applicant uses fraudulent documents to apply for registration of free sale.

2. The free sale of 03 batches of the medical equipment are forced to suspend from sale within the effective period of the registration number, applicable to types B, C or D medical equipment, or for 05 years, applicable to type A medical equipment, unless the holder of the free-sale registration number voluntarily recalls the equipment as prescribed in Article 32 of this Decree.

3. The applicant falsifies the contents of the free-sale registration number without permission.

4. The holder of the free-sale registration number terminates its operation or is no longer authorized by the owner of the medical equipment and no substitute organization has been appointed, except for cases specified in Article 34 of this Decree.

5. Quality of medical equipment being sold on market is not consistent with the registration quality.

6. The registration number has been issued against provisions of this Decree.

7. The owner of the free-sale registration number or the distributing establishment of the medical equipment has not given undertakings as prescribed in clauses 1 and 2 Article 34 of this Decree.

8. The time limit for free sale of the medical equipment specified in clauses 1 and 2 Article 34 of this Decree has expired.

9. The medical equipment was manufactured at an establishment unconformable to requirements specified in this Decree.

Article 36. Procedures for revocation of free-sale registration number

1. During the inspection, if any case specified in clauses 1, 2, 3, 4, 5, 6 and 8 Article 35 of this Decree is discovered, the agency conducting the inspection shall send an inspection record to the Ministry of Health or the Department of Health having issued the free-sale registration number (hereinafter referred to as the freee-sale registration number issuer).

2. Within 05 working days from the day on which the record specified in clause 1 of this Article is issued, the free-sale registration number issuer shall consider deciding the revocation of the free-sale registration number within its management.

3. After issuing the decision to revoke the registration number, the agency issuing the decision on revocation shall:

a) Publish on the web portal of the registration number issuer the decision on revocation of free-sale registration number and send such decision to the holder of the free-sale registration number, the Ministry of Health and other Departments of Health nationwide;

b) Annul information related to medical equipment which has been posted on the web portal of the freee-sale registration number issuer.

4. When the decision to revoke the free-sale registration number made by the free-sale registration number issuer has been received, Departments of Health shall publish it on the web portal and direct professional bodies to supervise the revocation of the medical equipment.

Chapter V

MANAGEMENT OF TRADING OF MEDICAL EQUIPMENT

Section 1. CONDITIONS FOR TRADING MEDICAL EQUIPMENT

Article 37. Type B, C or D medical equipment trading establishments

As establishment must satisfy the following conditions to trade in Type B, C or D medical equipment:

1. Having technical staff with acceptable qualifications for installing or guiding the use of medical equipment which such establishment trades, at least 01 of whom has the qualifications of technology or medicine/pharmacy of college or higher level or has the qualifications of medical equipment technology of college or higher level and his/her profession is conformable to the medical equipment which the establishment trades.

2. Having storage facilities conformable to the requirements specified in clause 3 Article 13 of this Decree and having vehicles for delivering equipment conformable to requirements specified in clause 4 Article 13 of this Decree, unless otherwise prescribed by laws. If the establishment does not have storage facilities or vehicles, a contract with an establishment capable of storing and transitting medical equipment shall be concluded.

Article 38. Procedures for declaration of eligibility to trade medical equipment

1. The declaration of eligibility to trade medical equipment shall consist of:

a) A declaration form of eligibility to trade medical equipment using the form No. 07 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree;

c) Papers proving that the storage facilities and vehicles are conformable to requirements specified in clauses 3 and 4 Article 13 of this Decree. Such papers shall be certified by the establishment declaring the eligibility to trade medical equipment.

2. Procedures for declaration of eligibility to trade medical equipment:

a) Before trading type B, C or D medical equipment, heads of medical equipment trading establishments shall send an declaration of eligibility to trade medical equipment specified in clause 1 of this Article to the Department of Health of the area where the trading establishent headquarters;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the receipt note using the form No. 05 in Annex IV enclosed with this Decree;

c) Within 03 working days from the day on which the declaration of eligibility to trade medical equipment, the Department of Health shall publish the following information onits web portal: name and address of the establishment trading medical equipment and the declaration of eligibility to trade medical equipment.

3. The establishment shall be allowed to trade type B, C or D medical equipment only when the procedures specified in point b clause 2 of this Article are fully conducted, except for cases specified in Article 39 of this Decree.

4. During its operation, if there is any change in employee staff, storage systemor transport vehicles, the trading establishment shall re-conduct the procedures for declaration of eligibility to trade medical equipment.

Article 39. Trade of type B, C or D medical equipment which is not required to satisfy conditions nor follow procedures for declaring eligibility to trade medical equipment

1. Type B, C or D medical equipment in the list of medical equipment issued by the Minister of Health shall be traded like other normal goods.

2. The trade of medical equipment specified in clause 1 of this Article is not required to satisfy conditions specified in Article 37 of this Decree and is not required to follow the procedures for declaring the eligibility to trade prescribed in Article 38 of this Decree, provided that such trading is conformable to the requirements for storage and transport precribed by the owner of the medical equipment.

Section 2. EXPORT AND IMPORT OF MEDICAL EQUIPMENT

Article 40. Rules on management of export/import of medical equipment

1. Any organization or individual exporting or importing medical equipment must satisfy conditions specified in laws on export and import and must assure the quality of the medical equipment that they exported/imported.

2. Medical equipment having got the registration number of free sale in Vietnam may be exported/imported on demand without limit on quantity and without approval by the Ministry of Health.

3. The Certificate of free sale shall only be issued to exported as prescribed by the Prime Minister.

4. The temporary import, temporary export or transit of medical equipment shall be carried out according to laws.

5. The import of used medical equipment shall be carried out according to laws.

Article 41. Export and import of medical equipment

1. The production of medical equipment for export is encouraged.

2. Any organization/individual importing medical equipment with the free-sale registration number must satisfy the following conditions:

a) Being the holder of the free-sale registration number or having the power of attorney made by the holder of the registration number. The holder of the free-sale registration number that authorize an importing establishment to import medical equipment shall send the power of attorney the Ministry of Health and the customs authority as well;

b) Having storage facilities conformable to the requirements specified in clause 3 Article 13 of this Decree and having vehicles for delivering equipment conformable to requirements specified in clause 4 Article 13 of this Decree or having the contract with the establishment capable of storing and transporting medical equipment.

3. The export and import of medical equipment shall comply with laws on customs. When conducting customs procedures, the organization importing medical equipment is not required to prove the conformity with conditions specified in clayse 2 of this Article.

Article 42. Import license

1. Cases in which a license to import medical equipment is required:

a) Such medical equipment does not have the free-sale registration number and is imported for scientific research or testing or for guiding the use of medical equipment or for reparing medical equipment;

b) Such medical equipment does not have the free-sale registration number and is imported to be used as aids;

c) Such medical equipment does not have the free-sale registration number and is imported for personal healthcare.

2. An applicaiton for the import license shall consist of:

a) A written application form for an import license using the form No. 08 provided in Annex I enclosed with this Decree;

b) Documents that give brief description of medical equipment technology using the forms provided in Annex VIII enclosed with this Decree and technical documents and instructioons for such medical equipment;

c) The Certificate of conformity with quality control standards of the establishment producing the medical equipment applying for the import license;

d) For medical equipment imported for research, a certified true copy of the decision on approval for the research project and documents proving that such products have been permitted in the exporting country by the competent agency;

dd) Regarding medical equipment imported to be use in training, the original copy of the training plan and documents proving that such products have been permitted in the exporting country by the competent agency;

e) For medical equipment imported to be used as aids, a copy of the decision on approval for aid receipt by the competent authority and documents proving that such products have been permitted in the exporting country by the competent agency ;

g) For cases where medical equipment is imported for personal healthcare, the prescription by the doctor .

3. Procedures for processing the application for the license for importing medical equipment:

a) After receiving the application, the Ministry of Health shall issue the applicant with the receipt note using the form No. 06 provided in Annex IV enclosed with this Decree;

b) If the application is not required to be amended, the Ministry of Health shall conduct inspection serving the issuance of the license for importing medical equipment within 15 working days from the date written on the receipt note. If the application is rejected, a written response containing explanation shall be made;

c) If the application is unsatisfactory, within 05 working days from the date written on the receipt note, the Ministry of Health shall send a written response to the applicant for completion. The notification shall specify the information to be supplemented and the information to be adjusted;

d) After receiving the request for modification of the application, the applicant shall modify the documents according to the written notification and re-send the application to the Ministry of Health. The date of receipt of the completed application shall be written on the receipt note;

If the application has been modified but unconformably with the request, the Ministry of Health shall notify the applicant for completing it;

After 60 days from the day on which the request of the Ministry of Health is received, if the applicant fails to complete the application, the procedures for applying for the import license shall be re-conducted.

dd) If the application is satisfactory, the Ministry of Health shall issue the license for importing medical equipment according to regulations in point b of this clause. The import license shall be sent to the applicant and the customs authority.

Article 43. Application for Certificate of free sale of domestically produced medical equipment

1. An application for the Certificate of free sale of medical equipment without the registration number shall include:

a) A written application form for the Certificate of free sale using the form No. 11 provided in Annex I enclosed with this Decree;

b) Documents specified in Article 22 (applicable to Type A medical equipment) or Article 26 (applicable to Type B, C or D medical equipment).

2. The application for the certificate of free sale of medical equipment must satisfy requirements specified in Article 23 (applicable to Type A medical equipment) or Article 28 (applicable to Type B, C or D medical equipment).

3. The application for the Certificate of Free sale of medical equipment with the registration number shall include the application form using the form No. 12 provided in Annex I enclosed with this Decree.

Article 44. Competence in and procedures for issuance, reissuance and revocation of the Certificate of free sale

1. The Minister of Health shall be responsible for the issuance, reissuance and revocation of the Certificate of free sale of medical equipment.

2. Procedures for issuance, reissuance and revocation of the Certificate of free sale shall comply with regulations of the Prime Minister on the issuance of Certificate of Free sale.

Section 3. RIGHTS AND OBLIGATIONS OF ORGANIZATIONS AND INDIVIDUALS TRADING MEDICAL EQUIPMENT

Article 45. Rights of establishments trading medical equipment

1. To request the medical equipment seller provides sufficiently information and documents to be used for tracing the origin and the warranty of medical equipment.

2. To request organizations/individuals importing, distributing or using products to cooperate with them in recalling and handling defective medical equipment.

3. To request the holder of the registration number of the medical equipment to provide warranty on the medical equipment.

4. To be notified by the holder of the registration number of the defective medical equipment.

5. Other rights as prescribed in laws.

Article 46. Obligations of establishments trading medical equipment

1. Conduct internal supervision to maintain the quality of medical equipment prescribed by the holder of the registration number.

2. Provide sufficiently and promptly information about:

a) Instruction on how to use the medical equipment; conditions for ensuring the safety, storing, calibrating, inspecting and maintaining medical equipment;

b) Give notification of defective medical equipment.

3. Retain medical equipment supervision dossier and trace the origin or recall medical equipment according to regulations in this Decree.

4. Promptly notify the holder of the free-sale registration number and the authority of the defective medical equipment.

5. Comply with laws and decisions on inspection issued by competent agencies.

6. Other obligations as prescribed in laws.

Chapter VI

MEDICAL EQUIPMENT SERVICES

Section 1. CONSULTANCY ABOUT MEDICAL EQUIPMENT TECHNOLOGY

Article 47. Conditions for providing consultancy services on medical equipment technology

1. The provision of services for consulting about the listing and formulation of technical structure and specifications of medical equipment technology shall be conducted by an individual who has been issued with the certificate of completing the training in consulting medical equipment technology.

2. Requirements applicable to individuals providing consultancy services on medical equipment technology:

a) Having university level qualifications specified in technique or medicine/pharmacy;

b) Having at least 5 years' experience of working in the field of medical equipment technology at a medical equipment-providing facility;

c) Having been tested and recognized by training institutions to be capable of consulting on medical equipment technology according to the training program issued by the Ministry of Health.

3. The consultant shall provide only consultancy on medical equipment technology when he/she has obtained the receipt note for the application for declaration of eligibility to provide consultancy about medical equipment technology as prescribed in point b clause 2 Article 48 of this Decree.

Article 48. Procedures for declaration of eligibility to provide consultancy on medical equipment technology

1. An application for declaration of eligibility to provide consultancy on medical equipment technology shall include:

a) An application form for declaration of eligibility to provide consultancy using the form No. 09 specified in Annex I enclosed with this Decree;

b) Certified true copies of qualificatioons specified in points a and c clause 2 Article 47 of this Decree;

c) A certificate of working time using the form in Annex II enclosed with this Decree.

2. Procedures for declaration of eligibility to provide consultancy on medical equipment technology:

a) Before providing consultancy on medical equipment technology, the applicant shall send the documents specified in clause 1 of this Article to the Ministry of Health;

b) If the application is satisfactory, the Ministry of Health shall issue the receipt note using the form No. 07 provided in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the receipt note, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the consultant; scope of consultancy on medical equipment technology and the declaration of eligibility to provide consultancy on medical equipment technology.

3. During its operation, if there is any change related to the accepted declaration, the consultant shall re-conduct the procedures for declaration of eligibility to provide consultancy on medical equipment technology.

Section 2. INSPECTION AND CALIBRATION OF MEDICAL EQUIPMENT

Article 49. Rules for inspection and calibration of medical equipment

1. Medical equipment shall be inspected according to laws on product quality and shall be calibrated according to regulations by the menufacturer, except for cases specified in clause 2 of this Article.

2. The inspection and calibration of medical equipment being measurement instruments or radiological equipment shall comply with regulations on measuring and atomic energy.

3. The inspection of medical equipment shall be conducted by establishments which have declared the eligibility to provide services on inspection and calibration for medical equipment.

4. The calibration of medical equipment shall be conducted by an establishment which has declared the eligibility to provide services on inspection and calibration for medical equipment or by the warranty provider of the holder of the registration number of free sale of the medical equipment.

Article 50. Requirements for establishments conducting inspection and calibration of medical equipment

1. Employees:

There shall be at least 2 technical employees (civil servants or employees working under contracts which are valid for 12 months or more or employees working under indefinite contracts) who satisfy the following conditions:

a) Having qualifications of college or higher level specified in technique or medicine/pharmacy;

b) Having professions suitable for the medical equipment he/she is assigned to inspected/calibrated.

2. Facilities and equipment:

There shall be laboratories. The laboratory shall obtain the certificate of conformity with the national standard on competence of testing and calibration laboratories TCVN ISO/IEC 17025 or the international standard ISO/IEC 17025 (hereinafter referred to as the certirficate of conformity with testing and calibration standards).

3. The establishment shall carry out the inspection/calibration of medical equipment only when it has obtained the receipt note for the declaration of eligibility to conduct the inspection/calibration of medical equipment as prescribed in clause 2 of this Decree.

Article 51. Declaration of eligibility to conduct ispection/calibration

1. A declaration of eligibility to conduct the ispection/calibration shall consist of:

a) An application form for declaration using the form No. 10 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree;

c) The certificate of conformity with testing and calibration standards which is valid at the time of declaration.

2. Requirements for the declaration of eligibility to conduct the ispection/calibration:

a) Documents serving the declaration of eligibility to conduct the inspection/calibration shall be compiled into 01 dossier, readable and arranged in order specified in clause 1 of this Article; there shall be separators between different parts, there shall be cover pages and the table of contents;

b) Regarding the Certificate of conformity with testing and calibration standards: an original copy or a certified true copy or a copy certified by the applicant hall be included;

If the copy certified by the organization declaring the eligibility to conduct the inspection/calibration is used, at the time of submission of the declaration, the original copy shall be presented for comparison or data sources shall be provided so that the receiving body can check the validity of such documents.

Any Certificate of conformity with inspection/calibration standards which is not made in English nor Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

Article 52. Procedures for declaring the eligibility to conduct the ispection/calibration

1. Before conducting the inspection/calibration of medical equipment, heads of the inspection/calibration establishment shall send the application specified in clause 1 Article 51 of this Decree to the Ministry of Health.

2. If the declaration is satisfactory, the Ministry of Health shall issue the establishment with the receipt note using the form No. 08 in Annex IV enclosed with this Decree.

3. Within 03 working days from the date written on the slip of receiving, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the establishment conducting the inspecrtion/calibration of medical equipment; scope of the inspection/calibration and the declaration of eligibility to conduct the inspection/calibration.

4. During its operation, if there is any change related to the accepted declaration, the inspection/calibration establishment shall re-conduct the procedures for declaring the eligibility to conduct the inspection/calibration of medical equipment.

Chapter VII

INFORMATION AND LABEL OF MEDICAL EQUIPMENT

Article 53. Information about medical equipment

1. Information about medical equipment is for the purpose of providing healthcare practitioners and users with guidelines on the reasonable and safe use of medical equipment.

2. Information about medical equipment must be sufficient, objective, accurate, honest, understandable and must not cause misunderstanding.

3. Responsibility for communicating information about medical equipment:

a) The holder of the free-sale registration number and the trading establishment of the medical equipment shall publish the information about the level of risks and information related to the use of medical equipment;

b) Medical facility shall communicate information about medical equipment within their establishment;

c) Health workers shall communicate information about the level of risks of the use of type C or D medical equipment on the patients;

d) Medical equipment management agencies shall publish the information on medical equipment.

4. Any organization and individual communicatiing information about medical equipment must be responsible for the information it/he/she has provided.

5. The Minister of Health shall develop medical equipment information system.

Article 54. Labels of medical equipment

1. The labeling of medical equipment shall comply with regulations in Decree No. 89/2006/ND-CP dated August 30, 2006 by the Government on labeling of goods and the label must contain:

a) Name of the medical equipment;

b) The registration number of free sale of the medical equipment;

c) Name and address of the holder of the registration number of free sale of the medical equipment;

d) The origin of the medical equipment;

dd) Date of production or expiry date. The date of production and the expiry date must be written in the format [dd/mm/yyyy] or [mm/yyyy].

e) Number of batch or the seri number of the medical equipment;

g) Guidance for seeking information about the warranty provider, guidlines for using the medical equipment, technical documents serving the repair and maintenance according to regulations in clause 2 Article 17 of this Decree.

2. Medical equipment imported into Vietnam whose label does not contain sufficiently the information specified in clause 1 of this Article must be enclosed with a supplementary label containing such information written in Vietnamese and the original label of the equipment shall be retained.

Chapter VIII

MANAGEMENT AND USE OF MEDICAL EQUIPMENT AT MEDICAL FACILITIES

Article 55. Rules on management and use of medical equipment

1. The management and use of medical equipment must be conformable with the purposes, utilities, policies and economical and effective.

2. The inspection, maintenance, repair, verification and calibration must comply with regulations of the producer, unless otherwise prescribed by laws.

Regarding medical equipment with strict labour hygiene and safety requirements, apart from the regulations on inspection, maintenance, repair, verification and calibration specified in this Decree, laws on labour hygiene and safety shall be complied with as well.

3. Documents on medical equipment shall be compiled, managed and retained sufficiently; the settlement of medical equipment in kind or in cash shall be conducted according to current laws on accounting and statistics and other relevant law provisions; funding for the conduct of tasks specified in Clause 2 of this Article shall be secured.

4. Medical facilities shall submit to the inspectio and supervision of competent regulatory bodies specified in medical equipment management.

Article 56. Management and use of medical equipment at State medical facilities

Apart from complying with regulations in Article 55 of this Decree regarding the management and use of medical equipment, state medical facilities shall conform to the following regulations:

1. Medical equipment in state medical facilities shall be managed and used according to laws on the management and use of State-owned property.

2. Policies on management and use of medical equipment shall be published.

3. The investment in or the conduct of the purchase of medical equipment shall conform to the following rules:

a) The investment as well as the purchase of medical equipment shall be conformable to the functions, tasks and demand of the unit and current laws on bidding;

b) State medical facilities are encouraged to use domestically produced medical equipment. Regarding domestically produced medical equipment which is declared by the Ministry of Health to be conformable to the requirements on quality and supply, the bidding documents and the invitations for bid shall contain provisions that forbid the bidders from offering imported medical equipment.

Article 57. Powers and responsibilities of medical facilities in the management and use of medical equipment

1. A medical facility shall have the following powers:

a) To request the holder of the free-sale registration number to carry out the periodic maintenance during the warranty period;

b) To request the seller to supply technical documents about medical equipment;

c) To receive medical equipment that is used for scientific research or for guiding the use of medical equipment.

2. Medical facility shall have the following responsibilities:

a) Use and operate medical equipment according to the guidance by its owner;

b) Periodically maintain, inspect and calibrate medical equipment according to the guidance by its owner or according to laws;

c) Conduct testing and assessment of quality of medical equipment;

d) Report cases of defective medical equipment and other information at the request of competent agencies.

Chapter IX

ONLINE DECLARATION AND REGISTRATION

Article 58. Cases subject to online declaration, registration or licensing

1. Declaration of eligibility to classify medical equipment.

2. Declaration of eligibility to produce medical equipment.

3. Declaration of applicable standards for medical equipment.

4. Registration of free sale of medical equipment.

5. Declaration of eligibility to trade medical equipment.

6. Declaration of eligibility to provide consultancy on medical equipment technology.

7. Declaration of eligibility to conduct the inspection/calibration of medical equipment.

8. Application for the license to import medical equipment.

9. Application for the Certificate of free sale of domestically-produced medical equipment.

Article 59. Online application for declaration, registration or licensing

A valid online declaration, online application for registration of free sale, or issuance of the license or the Certificate of free sale (hereinafter referred to as the online registration application) shall satisfy the following requirements:

1. It contains sufficient documents according to regulations applicable to written application which are transformed into electronic documents. Such electronic documents shall be named according to the name of the form in the written application.

2. Information about the declaration, the application for registration or license shall be declared sufficiently and accurately according to information provided in the electronic documents.

Article 60. Procedures for online declaration

1. The legal representativeshall make declaration, download electronic documents, confirm with public digital signatures and pay charges according to the procedures specified on the web portal of the Ministry of Health or the Department of Health.

2. When the online application has been submitted, the representatives at law shall receive a receipt note.

3. The online application receiving body shall carry out administrative procedures for the application according to regulations in this Decree.

4. The result of the online administrative procedures is an electronic document with the digital signature of the receiving body and shall have legal effect like the one of the normal administrative procedures.

Article 61. Retention of online applications

1. In case of online application, the applicant shall retain the written documents of the application.

2. If any document of the registration dossier specified in clause 1 of this Article is lost or damaged, the registering establishment shall send a written notification to the receiving body, recomplete the dossier; when the application has been recompleted, the applicant shall notify the receiving body in writing and update the information after being approved by the receiving body.

3. Within 35 days from the day on which the notification of the loss of the application is received, if the applicant fails to issue a written notification of the recompletion of the application, the receiving body shall:

a) Annul information posted on the web portal that is related to the establishment conducting the classification of the medical equipment, the establishment producing the medical equipment, the establishment trading the medical equipment, the person/establishment providing the consultancy about the medical equipment technology, the establishment inspecting/calibrating the medical equipment, the registration number of free sale of the medical equipment;

b) Revoke the free-sale registration number and the import license of the medical equipment.

4. The registrering establishment shall not continue its operation and the medical equipment shall not be freely sold from the time the receiving body annuls the information as prescribed in clause 3 of this Article.

Chapter X

ORGANIZATION OF IMPLEMENTATION

Article 62. The Ministry of Health

The Ministry of Health shall be answerable to the Government for the management of medical equipment and shall have the following tasks and powers:

1. Request the Government or the Prime Minister to promulgate or promulgate by itself within their competence legislative documents, National technical regulation, strategies, policies and plans regarding medical equipment.

2. Direct and conduct the implementation of legislative documents, strategies, policies and plans regarding medical equipment.

3. Conduct the communication of information about medical equipment.

4. Provide training for human resources whose work involves medical equipment.

5. Publish on the web portal of the Ministry of Health information about:

a) The winning price of the bidding for medical equipment of medical facilities nationwide;

b) The list of medical equipment whose free-sale registration number has been revoked.

6. Conduct inspection, resolve complaints/denunciations and impose penalties for violations against laws pertaining to medical equipment.

7. Promote the international cooperation in medical equipment.

Article 63. The Ministry of Science and Technology

1. Issue the list of medical equipment and measurement instruments subject to obtaining model approval, inspection and/or calibration after receiving the opinion of the Ministry of Health.

2. Preside over or cooperate with the Ministry of Health in formulating national standards on medical equipment; conduct inspection of the quality of medical equipment being measurement instruments or radiological equipment.

Article 64. The Ministry of Finance

1. Guide the management of state property being medical equipment of state medical facilities after receiving the opinion of the Ministry of Health.

2. Provide detailed regulations on the management and use of charges and fees pertaining to medical equipment according to laws on charges and fees.

Article 65. People's Committees of provinces and central-affiliated cities

1. Manage activities related to the trade and use of medical equipment in local areas.

2. Conduct the communication of information about medical equipment in local areas.

3. Provide training for human resources whose work involves medical equipment in local areas.

4. Publish on the web portals of People's Committees of provinces or central-affiliated cities and send the Ministry of Health information about:

a) The winning prices of the bidding for medical equipment of medical facilities in local areas;

b) The list of medical equipment whose registration number has been revoked within local areas..

5. Conduct inspection, resolve complaints/denunciations and impose penalties for violations against laws pertaining to medical equipment in local areas.

Article 66. Organizations and individuals trading medical equipment

1. Organizations and individuals trading medical equipment shall be responsible for the safety and quality of medical equipment they trade.

2. Holders of the free-sale registration numbers shall:

a) Publish the applicable standards or conduct the registration of free sale of medical equipment according to regulations of this Decree;

b) Establish and maintain the medical equipment warranty providers or conclude contracts with medical equipment warranty providers;

c) Formulate and retain medical equipment supervision dossiers and trace the origin of medical equipment according to regulations in this Decree, except for disposable medical equipment as prescribed by the owners of the medical equipment;

d) Print sufficiently and accurately information about the products on their labels or their enclosed documents according to laws on labeling and provisions of this Decree;

dd) Promptly give sufficient and accurate warning about the risks of causing bad effect on users' health and on the environment ; guide the sellers and the consumers to prevent; provide information about requirements applicable to the transport, storage and use of medical equipment;

e) Promptly terminate the free sale of equipment, notify relevant parties and take measures to handle or eliminate the issues or recall the defective equipment as provided for in this Decree. In cases where medical equipment is to be destroyed, such destruction must comply with laws on environmental protection and relevant law provisions. The owners of the registration numbers shall pay fully the cost of such destruction activity;

g) Comply with laws and decisions on inspection issued by competent agencies;

h) Provide compensation according to laws in case of defection of the medical equipment;

i) Take responsibility for ensuring that the following papers are kept valid during the validity of the free-sale registration numbers:

- The Certificate of conformity with quality control standards of the establishment producing the medical equipment;

- The Certificate of free sale, applicable to type B, C or D imported medical equipment;

- The power of attorney, except for cases specified in point a clause 1 Article 21 of this Decree;

- The Certificate of eligibility to provide warranty.

k) Other obligations as prescribed by laws.

3. The representative offices of the holders of the free-sale registration numbers shall fully implement the obigations specified in clause 2 of this Article.

Chapter XI

IMPLEMENTARY CLAUSE

Article 67. Effect

1. This Decree comes into effect from July 01, 2016.

2. Clause 10 Article 12 of Decree No. 89/2006/ND-CP dated August 30, 2006 by the Government shall be annulled by the effect of this Decree.

Article 68. Transitional clause

1. A producer of medical equipment which has operated before the effective date of this Decree may continue its operation, provided that the declaration of eligibility to produce medical equipment is maded before July 01, 2017.

Particularly regarding regulations on the quality control system: the producers of medical equipment shall complete the application of the ISO 9001 quality control system before January 01, 2018 and the ISO 13485 the quality control system before January 01, 2020.

2. Trading establishments which has operated before the effective date of this Decree may continue their operation, provided that the annoucement of eligibility to trade medical equipmen has been made according to regulations in this Decree before January 01, 2017.

3. Providers of medical equipment services that have operated before the effective date of this Decree may continue their service provision, provided that they have submitted the application for declaration of eligibility to provide consultancy about medical equipment technology or of the eligibility to conduct the inspection/calibration of medical equipment before July 01, 2017.

4. Medical equipment produced in Vietnam or imported into Vietnam before the effective date of this Decree are allowed to be sold freely until it is disposed as prescribed in clause 1 Article 22 of the Law on the management and use of State-owned property or until the expiry date written on the certificate of free sale registration.

5. The issuance of the license for importing medical equipment or the issuance of the registration number of free sale of medical equipment which is domestically produced or in vitro diagnostic reagents shall comply with current law provisions until the expiration of the period specified in clause 6 of this Article. Validity periods:

a) An import license shall be effective until June 30, 2017, for Type A medical equipment, or December 31, 2017, for Type B, C and D medical equipment, except for cases specified in clause 1 Article 42 of this Decree;

b) The registration number of free sale of domestically produced medical equipment or in vitro diagnostic reagents shall be effective until the expiry date written on the Certificate of free sale registration.

6. Declarations of applicable standards for Type A medical equipment shall be received since January 01, 2017 and the corresponding receipt notes shall be effective since July 01, 2017; the application for registration of free sale of Type B, C or D medical equipment shall be received since July 01, 2017 and the registration numbers of free sale of medical equipment shall be effective from January 01, 2018.

7. The labels of the medical equipment produced in Vietnam or imported into Vietnam before the date specified in clause 5 of this Article are accepted until the expiry date of the medical equipment or until the medical equipment is disposed as prescribed in clause 1 Article 22 of the Law on the management and use of State-owned property or until the expiry date written on the certificate of free sale registration.

Article 69. Responsibility for guiding and implementing

1. The Minister of Health shall be responsible for guiding and monitoring the implementation of this Decree.

2. Ministers, Heads of ministerial-level agencies, Heads of Governmental agencies, Presidents of People's Committees of all levels and relevant agencies, organizations and individuals shall be responsible for implementing this Decree./

ON BEHALF OF THE GOVERNMENT
THE PRIME MINISTER

Nguyen Xuan Phuc

ANNEX I

FORMS OF DECLARATIONS, APPLICATIONS FOR LICENSING, APPLICATIONS FOR ISSUANCE OF CERTIFICATE OF FREE SALE

(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Form No. 01 Declaration of eligibility to classify medical equipment.

Form No. 02	Declaration of eligibility to produce medical equipment.
Form No. 03	Declaration of applicable standards of type A medical equipment
Form No. 04	Application for the registration number of medical equipment
Form No. 05	Application for reissuance of the registration number of medical equipment
Form No. 06	Application for extension of the registration number of medical equipment
Form No. 07	Declaration of eligibility to trade medical equipment
Form No. 08	Application for the permit to import medical equipment.
Form No. 09	Declaration of eligibility to provide consultancy on medical equipment technology
Form No. 10	Declaration of eligibility to conduct the inspection/calibration of medical equipment
Form No. 11	Application for the Certificate of free sale for medical equipment without the registration number
Form No. 12	Application for the Certificate of free sale for medical equipment with the registration number

Form No. 01

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1].....,.....[Date].....

DECLARATION OF ELIGIBILITY TO CLASSIFY MEDICAL EQUIPMENT

To: The Ministry of Health (the Department of Medical Equipment and Works)

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: [2].....

Phone number: ..... Fax: .....

Email: ……. Website (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Classifying technician(s)[3]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Professional ability: .....

Experience of working in field of medical equipment: .....month(s).

Hereby declare the eligibility to classify medical equipment

Attachments:

1.	List of employees
2.	Certificate of experience (working time)
3.	Qualifications of each classifying technician

We - the establishment declaring eligibility to classify medical equipment - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. The classification of medical equipment is conducted according to laws. We will take wholly the responsibility for the results of classification we conducted.

3. Any change related to the information in the declaration will be notified to the Ministry of Health (the Department of Medical Equipment and Works).

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The address written on the enterprise registration certificate is required

3. All the technicians shall be specified

Form No. 02

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

DECLARATION OF ELIGIBILITY TO PRODUCE MEDICAL EQUIPMENT

To: .....[2].....

1. Name of establishment: .....

Tax codes: .....

Address:
..... [3] .....
.

Address of establishment: .....[4].....

Phone number: ..... Fax: .....

Email: …… Website (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Professional:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Professional ability: .....

Experience of working in field of medical equipment: .....month(s).

4. Medical equipment produced by establishment:

No.	Name of medical equipment	Expected scale (pcs/year)
1		
2		

Hereby declare the eligibility to produce medical equipment

Attachments:

1.	List of employees
2.	Documents on assignment and appointment of professionals of the establishment
3.	Qualifications pertaining to medical equipment technology or medical equipment management of the professionals
4.	Certificates of experience (working time) of the professionals
5.	Certificate of conformity with quality control standards[5]
6.	Documents proving that conditions of location, area and factory are suitable for the medical equipment that the establishment produces
7.	Documents about equipment and manufacturing and quality inspection procedures suitable for the medical equipment that the establishment produces

8.	Contracts with eligible establishments for conducting quality inspection of medical equipment that the establishment produces
9.	Documents on storage facilities for medical equipment
10.	Documents on transport vehicles for medical equipment

We - the establishment declaring eligibility to produce medical equipment - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Declared conditions are ensured and maintained during our operation.

3. Any change related to the information in the declaration will be notified to the Department of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered

3. The address written on the Certificate of Business registration is required

4. If such address is the same as the one written on the Certificate of Business registration, write "tại trụ sở" (at the headquarter)

5. If such document is unavailable, documents specified in rows 6, 7, 8, 9 and 10 are required

Form No. 03

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1].....,.....[Date].....

DECLARATION OF APPLICABLE STANDARD FOR TYPE A MEDICAL EQUIPMENT

To: .....[2].....

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address:
.....[3].....
.

Phone number (landline): ..... Fax: .....

Email:.....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Type A medical equipment:

Name of the medical equipment: .....

Model/code of product:.....

Packaging specifications (if any): .....

Name of establishment: .....

Address of establishment: .....

Applicable standard: .....

4. Information about the owner of the medical equipment:

Name: .....

Address: .....

5. Information about warranty establishment:

Name: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

Hereby declare the applicable standard for type A medical equipment

Attachments:

1.	Classification table of medical equipment
2.	Note of receipt of the declaration of eligibility to produce medical equipment
3.	Certificate of conformity with quality control standards
4.	LETTER OF AUTHORIZATION by the owner of the medical equipment
5.	Certificate of eligibility to provide warranty
6.	Documents containing technical summary of the medical equipment
7.	The standard which the owner of the medical equipment declares to apply
8.	Certificate of conformity
9.	Written instruction for the medical equipment
10.	Sample of the label of the medical equipment

We - the establishment declaring the applicable standard for type A medical equipment - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical equipment receives quality assurance and is sold according to the declared information.

3. Any change related to the information in the declaration will be notified to the Department of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

---

1. Location

2. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

3. The address written on the Certificate of Business registration is required

Form No. 04

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

APPLICATION FOR ISSUANCE OF REGISTRATION NUMBER OF MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Phone number: ..... Fax: .....

Email:.....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Medical equipment to be registered:

Name of the medical equipment: .....

Model: .....

Packaging specifications (if any): .....

Type of medical equipment: .....

Name of manufacturer: .....

Address of manufacturer: .....

4. Information about the owner of the medical equipment:

Name: .....

Address: .....

5. Information about warranty establishment:

Name: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

Attachments:

1.	Classification table of medical equipment
2.	Certificate of conformity with quality control standards
3.	LETTER OF AUTHORIZATION by the owner of the medical equipment
4.	Certificate of eligibility to provide warranty
5.	Certificate of free sale for imported medical equipment
6.	Documents containing technical summary of the medical equipment
7.	Documents containing description of technical features of the medical equipment
8.	Written instruction for the medical equipment
9.	Summary of data on clinical test of types C and D medical equipment used by putting into human bodies
10.	Certificate of inspection, applicable to medical equipment used for types C and D in-vitro diagnosis
11.	Sample of the label of the medical equipment
12.	Certificate of conformity
13.	Decision to approve the model

We - the establishment applying for the registration number of medical equipment - undertake that:

1. The provided information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical equipment receives quality assurance and is sold according to the registration dossier.

3. Any change related to the information in the application will be notified to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The address written on the Certificate of Business registration is required

Form No. 05

Name of establishment **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

APPLICATION FOR REISSUANCE OF REGISTRATION NUMBER OF MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Hereby apply for reissuance of the registration number of medical equipment:

Number of the obtained certificate of registration for sale:.....

Date of issue: ..... Effective duration: .....

Reasons for applying for reissuance of the registration number of medical equipment:
.....

We undertake that these information above is truthful. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The address written on the Certificate of Business registration is required

Form No. 06

Name of establishment **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

APPLICATION FOR EXTENSION OF THE REGISTRATION NUMBER OF MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Hereby apply for extension of the registration number of medical equipment:

The obtained registration number: .....

Date of issue: ..... Effective duration: .....

Date of 1st extension: ..... Effective duration: .....

Date of 2nd extension: ..... Effective duration: .....

Attachments:

1.	The obtained certificate of registration for sale
2.	Certificate of conformity with quality control standards
3.	LETTER OF AUTHORIZATION by the owner of the medical equipment
4.	Certificate of free sale for imported medical equipment
5.	Income statement

We - the establishment applying for the registration number of medical equipment - undertake that:

1. The provided information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical equipment receives quality assurance and is sold according to the registration dossier.

3. Any change related to the information in the application will be notified to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The address written on the Certificate of Business registration is required

Form No. 07

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., *.....[Date].....*

DECLARATION OF ELIGIBILITY TO TRADE MEDICAL EQUIPMENT

To: .....[2].....

1. Name of establishment: .....

Tax codes: .....

Address: ……[3].....

Transaction office (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Technicians of the trading establishment[4]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Professional ability: .....

4. List of medical equipment traded by the establishment:

.....

.....

.....

Hereby declare the eligibility to trade medical equipment

Attachments:

1.	List of employees
2.	Documents on storage facilities for medical equipment
3.	Documents on transport vehicles for medical equipment

We - the establishment declaring eligibility to trade medical equipment - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical equipment receives quality assurance and is sold according to the laws.

3. Any change related to the information in the declaration will be notified to the Department of Health of .....[5].....

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

3. The address written on the Certificate of Business registration is required

4. All the technicians shall be specified

5. The province/central-affiliated city where the establishment is headquartered

Form No. 08

Name of importing organization/individual	**SOCIALIST REPUBLIC OF VIETNAM**
--------	**Independence - Freedom - Happiness**

No.:	*.....[1].....,.....[Date].....*

APPLICATION FOR THE PERMIT TO IMPORT MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

Name of importing organization/individual: .....

Tax codes or National ID number/ Passport number: .....

Lawful representative: .....

Contact number: .....

Hereby apply for the permit to import the following medical equipment:

No.	**Name of medical equipment**	**Model**	**Manufacturer, Country of origin**	**Owner**	**Distributor** *(if any)*	**Quantity**

1. Importing purpose: .....

2. User: …….....

3. I/We - the importing organization/individual - hereby undertake to:

- Take responsibility for ensuring the quality, model, quantity of imported medical equipment.

- Ensure the proper use of imported medical equipment.

I/We will take all legal responsibility for any violation I/we commit.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

Form No. 09

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

DECLARATION OF ELIGIBILITY TO PROVIDE CONSULTANCY ON MEDICAL EQUIPMENT TECHNOLOGY

To: The Ministry of Health (Department of Medical Equipment and Works).

1. Provider of consultancy about medical equipment technology:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Address: .....

Phone number: ..... Email: .....

Professional ability: .....

2. Scope of consultancy:

No.	Content of consultancy	Medical equipment technology serving the consultancy
1	Consultancy about formulation of list of medical equipment	
2	Consultancy about formulation of configuration and technical features of medical equipment	

Hereby declare the eligibility to provide consultancy on medical equipment technology

Attachments:

1.	Qualifications of the consultancy provider
2.	Certificate of experience (working time)

I undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, I will take wholly the responsibility and will incur penalties according to laws.

2. Any change in the declaration of eligibility to provide consultancy about medical equipment technology will be reported to the Ministry of Health.

The consultancy provider
(Signature and full name)

_____

1. Location

Form No. 10

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

DECLARATION OF ELIGIBILITY TO CONDUCT THE INSPECTION/CALIBRATION OF MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

1. Name of establishment: .....

Tax codes: .....

Address: ……[2].....

Transaction office (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Technicians of the trading establishment[3]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Professional ability: .....

4. Scope of inspection: List of medical equipment subject to inspection by the eligible establishment

.....

.....

.....

5. Scope of calibration:

……[4].....

.....

.....

Hereby declare the eligibility to conduct the inspection/calibration of medical equipment

Attachments:

1.	List of employees
2.	Certificate of conformity with testing and calibration standards

We - the establishment declaring the eligibility to conduct the inspection/calibration of medical equipment - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Declared conditions are ensured and maintained during our operation.

3. Any change in the declaration of eligibility to conduct inspection/calibration of medical equipment will be reported to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

---

1. Location

2. The address written on the Certificate of Business registration is required

3. All the technicians shall be specified

4. The list of medical equipment subject to inspection by the eligible establishment is required

Form No. 11

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]....., ...[Date].....

APPLICATION FOR THE CERTIFICATE OF FREE SALE FOR MEDICAL EQUIPMENT WITHOUT THE REGISTRATION NUMBER

To: The Ministry of Health (Department of Medical Equipment and Works)

1. Name of establishment: .....

Tax codes: .....

Address (according to the business registration): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Manufacturer:

Name of establishment: .....

Address of the headquarter (according to the business registration): .....

Address of manufacture place: .....

Phone number: ..... Fax: .....

To fulfill the requirements of the importing country, we hereby apply for the Certificate of free sale (CFS) for the following medical equipment:

No.	Name of medical equipment	Model	Type	Importing country
1				
2				

We commit ourselves to taking legal responsibility for the information declared above.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

Form No. 12

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

APPLICATION FOR THE CERTIFICATE OF FREE SALE FOR MEDICAL EQUIPMENT WITH THE REGISTRATION NUMBER

To: The Ministry of Health (Department of Medical Equipment and Works)

1. Name of establishment: .....

Tax codes: .....

Address (according to the business registration): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Manufacturer:

Name of establishment: .....

Address of the headquarter (according to the business registration): .....

Address of manufacture place: .....

Contact number: ..... Fax: .....

To fulfill the requirements of the importing country, we hereby apply for the Certificate of free sale (CFS) for the following medical equipment:

No.	Name of medical equipment	Model	Type	Registration number	Importing country

1					
2					

We commit ourselves to taking legal responsibility for the information declared above.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

ANNEX II

LIST OF EMPLOYEES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

LIST OF EMPLOYEES

Name of establishment: .....

Address: .....

No.	Full name	Position	Qulification	Experience of working in field of medical equipment				Training in medical equipment				
				Unit	Working period	Position	Main task	Name of training institution	Speciality	Qualification	Form of training	Time of training
1												
2												
3												

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

ANNEX III

CERTIFICATE OF WORKING TIME
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

CERTIFICATE OF WORKING TIME

To: .....[2].....

My name is: .....

Date of birth: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

I hereby apply for your verification of the following information:

I am working/worked for: .....

From .....[date].....to.....[date].....

Position: .....

Main task: .....

.....

.....

I look forward to your support.

Best regards!

....., ...[Date].....

VERIFIED BY	**APPLICANT**
(Signature, full name, verification of the unit)	*(Signature and full name)*

_____

1. Location

2. Name of the unit where the applicant works is required

ANNEX IV

MODELS OF NOTES OF RECEIPT OF AN APPLICATION, CERTIFICATE OF REGISTRATION FOR SALE
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Form No. 01	Note of receipt of the declaration of eligibility to classify medical equipment
Form No. 02	Note of receipt of the declaration of eligibility to produce medical equipment
Form No. 03	Note of receipt of the declaration of applicable standard for type A medical equipment
Form No. 04	Note of receipt of the application for registration number of medical equipment

Form No. 05	Note of receipt of the declaration of eligibility to trade medical equipment
Form No. 06	Note of receipt of the application for the permit to import medical equipment
Form No. 07	Note of receipt of the application for declaration of eligibility to provide consultancy on medical equipment
Form No. 08	Note of receipt of the declaration of eligibility to conduct the inspection/calibration of medical equipment
Form No. 09	The Certificate of registration for sale

Form No. 01

THE MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

Ha Noi, [date]

RECEIPT NOTE FOR THE DECLARATION OF ELIBILITY TO CLASSIFY MEDICAL EQUIPMENT

1. Name of the establishment: .....

2. Address: .....

3. Phone: ..... Fax: .....

4. Number of the application of the establishment: ..... Date: .....

5. Components of the application:

1.	Declaration of eligibility to classify medical equipment	□
2.	List of employees	□
3.	Certificate of working time	□
4.	Qualifications of each classifying technician	□

RECEIVING OFFICER
(Signature, position and full name)

Form No. 02

DEPARTMENT OF HEALTH OF
....[1].....

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

RECEIPT NOTE FOR THE DECLARATION OF ELIGIBILITY TO PRODUCE MEDICAL EQUIPMENT

1. Name of manufacturer: .....

2. Address: .....

3. Phone: ..... Fax: .....

4. Number of the application of the establishment: ..... Date: .....

5. Name of the equipment to be produced by the establishment:

.....

6. Components of the application:

1.	Declaration of eligibility to produce medical equipment	□
2.	List of employees	□
3.	Documents on assignment and appointment of professionals of the establishment	□
4.	Certificate of working time	□
5.	Qualifications pertaining to medical equipment technique or medical equipment management of the professionals	□
6.	Certificate of conformity with quality control standards	□
7.	Documents proving that conditions of location, area and factory are in conformity with the requirements of medical equipment that the establishment produces	□
8.	Documents about equipment and manufacturing and quality inspection procedures suitable for the medical equipment that the establishment produces.	□
9.	Contracts with eligible establishments for conducting quality inspection of medical equipment that the establishment produces	□
10.	Documents on storage facilities for medical equipment	□
11.	Documents on transport vehicles for medical equipment	□

RECEIVING OFFICER
(Signature, position and full name)

_____

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 03

DEPARTMENT OF HEALTH OF
....[1].....

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

---------- **----------**

No.: ....[2]....., ...*[Date]*.....

RECEIPT NOTE FOR THE DECLARATION OF APPLICABLE STANDARD FOR TYPE A MEDICAL EQUIPMENT

1. Name of the establishment: .....

2. Address: .....

3. Number of the application of the establishment: ..... Date: .....

4. Type A medical equipment:

Name of the medical equipment: .....

Model/code of product:.....

Name of manufacturer: .....

Address of manufacturer: .....

Applicable standard: .....

5. Information about the owner of the medical equipment:

Name: .....

Address: .....

6. Information about warranty establishment:

Name of establishment: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

7. Components of the application:

1	Application for declaration of applicable standards of type A medical equipment	□
2	Classification table of medical equipment	□
3	Note of receipt of the declaration of eligibility to produce medical equipment	□
4	Certificate of conformity with quality control standards	□
5	LETTER OF AUTHORIZATION by the owner of the medical equipment	□
6	Certificate of eligibility to provide warranty	□
7	Documents containing technical summary of the medical equipment	□
8	The standard which the owner of the medical equipment declares to apply	□
9	Certificate of conformity	□
10	Written instruction for the medical equipment	□

11	Sample of the label of the medical equipment	□

RECEIVING OFFICER
(Signature, position and full name)

---

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 04

THE MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

Ha Noi, [date]

RECEIPT NOTE FOR THE APPLICATION FOR REGISTRATION NUMBER OF MEDICAL EQUIPMENT

1. Name of establishment: .....

2. Address: .....

3. Number of the application of the establishment: ..... Date: .....

4. Application for registration for sale of medical equipment in different cases:

1.	Application for issuance of the registration number	□
2.	Application for extension of the registration number	□
3.	Application for reissuance of the registration number	□

5. Components of the application:

1.	Application for the registration number	□
2.	Classification table of medical equipment	□
3.	Certificate of conformity with quality control standards	□
4.	LETTER OF AUTHORIZATION by the owner of the medical equipment	□
5.	Certificate of eligibility to provide warranty	□
6.	Certificate of free sale for imported medical equipment	□
7.	Documents containing technical summary of the medical equipment	□

8.	Documents containing description of technical features of the medical equipment	□
9.	Written instruction for the medical equipment	□
10.	Summary of data on clinical test of types C and D medical equipment used by putting into human bodies	□
11.	Certificate of inspection, applicable to medical equipment used for types C and D in-vitro diagnosis	□
12.	Sample of the label of the medical equipment	□
13.	Certificate of conformity	□
14.	Decision to approve the model	□

RECEIVING OFFICER
(Signature, position and full name)

Form No. 05

DEPARTMENT OF HEALTH OF
....[1].....

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[2]....., ...[Date].....

RECEIPT NOTE FOR THE DECLARATION OF ELIGIBILITY TO TRADE MEDICAL EQUIPMENT

1. Name of the trading establishment: .....

2. Address: .....

4. Number of the application of the establishment: ..... Date: .....

4. Components of the application:

1.	Declaration of eligibility to trade medical equipment	□
2.	List of employees	□
3.	Certificate of working time	□
4.	Qualifications pertaining to medical equipment technology or medical equipment management of the professionals	□
5.	Documents on storage facilities for medical equipment	□
6.	Documents on transport vehicles for medical equipment	□

RECEIVING OFFICER
(Signature, position and full name)

---

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 06

THE MINISTRY OF HEALTH **----------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.: ...../NKTTBYT	*Ha Noi, [date]*

RECEIPT NOTE FOR THE APPLICATION FOR THE PERMIT TO IMPORT MEDICAL EQUIPMENT

1. Name of importing organization/individual: .....

2. Tax codes or National ID number/ Passport number: .....

3. Number of the application of the organization/individual: ..... Date: .....

4. Medical equipment to be imported: .....

No.	Name of medical equipment
1.	
2.	

RECEIVING OFFICER
(Signature, position and full name)

Form No. 07

THE MINISTRY OF HEALTH **----------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	*Ha Noi, [date]*

RECEIPT NOTE FOR THE DECLARATION OF ELIGIBILITY TO PROVIDE CONSULTANCY ON MEDICAL EQUIPMENT TECHNOLOGY

1. Provider of consultancy about medical equipment technology:

Full name: .....

Address: .....

Phone: .....

2. Scope of consultancy: .....

3. Components of the application:

1.	Application for certificate of eligibility to provide consultancy	□
2.	Qualifications of the consultancy provider	□
3.	Certificate of working time	□

RECEIVING OFFICER
(Signature, position and full name)

Form No. 08

THE MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

Ha Noi, [date]

RECEIPT NOTE FOR THE DECLARATION OF ELIGIBILITY TO CONDUCT THE INSPECTION/CALIBRATION OF MEDICAL EQUIPMENT

1. Name of the establishment conducting the inspection/calibration: .....

2. Address: .....

3. Phone: .....

4. Scope of inspection: .....

5. Scope of calibration: .....

6. Components of the application:

1	Application for certificate of eligibility to conduct inspection/calibration	□
2	List of employees	□
3	Certificate of conformity with testing and calibration standards	□

RECEIVING OFFICER
(Signature, position and full name)

Form No. 09

THE MINISTRY OF HEALTH **----------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	*Ha Noi, [date]*

CERTIFICATE OF REGISTRATION FOR SALE OF MEDICAL EQUIPMENT

Pursuant to Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government on management of medical equipment.

The Ministry of Health issue the certificate of registration for sale of new medical equipment as follows:

1. Name of medical equipment:

2. Model/code of product:

3. Packaging specifications (if any):

4. Type:

5. Name and address of the manufacturer:

6. Name and address of the owner of the medical equipment:

7. Name and address of the holder of the registration number:

8. Name and address of the warranty establishment:

The registration number is effective from:.....to.....

Receiver:	**[POSITION OF THE SIGNER]** [Full name, title] (Verified with seal or digital signature)

ANNEX V

CLASSIFICATION OF MEDICAL EQUIPMENT
(*Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)*

[Name].....[1]..... **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.: ....[2]..../....[3].....	*.....[4]....., ...[Date].....*

CLASSIFICATION OF MEDICAL EQUIPMENT

To: .....[5].....

Pursuant to Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government on management of medical equipment;

Rules for classification: .....[6].....

We hereby classify medical equipment as follows:

No.	Name of medical equipment	Model/code of product	Manufacturer, Country of origin	Owner	Type

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

Receiver:
.....

_____

1. Name of the establishment which has declared the eligibility to classify medical equipment is required

2. Symbol of the document containing the classification result which is under the management of the eligible establishment

3. Code of the establishment eligible to classify is the number of the receipt note for the declaration of eligibility to classify medical equipment issued by the Ministry of Health

4. Location

5. Name of the establishment applying for classification of medical equipment

6. The rules used for classifying medical equipment as guided by the Ministry of Health shall be specified

ANNEX VI

LETTER OF AUTHORIZATION
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the owner of the medical equipment

.....[Date].....

LETTER OF AUTHORIZATION

To: .....

We, *(name and address of the owner)*, as the owner of the medical equipment, hereby authorize *(name and address of the establishment declaring the applicable standard or applying for registration number)* to sell in Vietnam's market the following medical equipment:

.....(the medical equipment shall be listed[1]).....

We hereby undertake to provide and assist the fulfillment of requirements related to the information and quality and ensure the requirements pertaining to warranty and maintenance and supply of materials and substitutes for such medical equipment. This LETTER OF AUTHORIZATION is effect until: ..... [date]

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. The list of medical equipment under authorization may be performed as an annex enclosed with the LETTER OF AUTHORIZATION

ANNEX VII

CERTIFICATE OF ELIGIBILITY TO PROVIDE WARRANTY
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the owner of the medical equipment: .....

.....[Date].....

CERTIFICATE OF ELIGIBILITY TO PROVIDE WARRANTY

Name: .....

Address: .....

as the owner of the medical equipment, hereby verify that the following establishments are elibigle to provide warranty for medical equipment of .....[1].....:

Name of medical equipment	Name of establishment	Tax codes	Address	Phone number (landline)	Phone number (mobile)
…..	Establishment No. 1				
	Establishment No. 2				
…..	Establishment No. 1				
	Establishment No. 2				
	Establishment No. 3				
…..	…..				

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Full name and address of the owner of the medical equipment are required

ANNEX VIII

TECHNICAL DOCUMENTS OF MEDICAL EQUIPMENT
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Form No. 01 Documents containing technical summary of the medical equipment

Form No. 02 Technical documents for reagents, calibration solutions, in-vitro control materials

Form No. 01

DOCUMENTS CONTAINING TECHNICAL SUMMARY OF THE MEDICAL EQUIPMENT

Name and address of the establishment applying for the registration number of the medical equipment

.....[Date].....

No.	Heading	Content
1	Description of medical equipment	
1.1	Description of medical equipment	Brief descriptiono of operating principle and features and technical parameters of the equipment; if the medical equipment involves novel technology, the description of such technology shall be provided (for example nanotechnology)
1.2	List of accessories and fittings	List of accessories and fittings of medical equipment
1.3	Purposes/Instruction	Purposes of the medical equipment and instruction for use thereof
1.4	Instruction	Summary of instruction to use the equipment accoridng to the Instruction sheet or the Information sheet of the medical equipment
1.5	Contraindications	Information about contraindications - cases where the equipment must not be used so as for the safety of the patient, e.g. due to anamnesis or physiological features of the patient, etc.; in accordance with the contents approved at the country of manufacture and displayed on the label of the equipment
1.6	Warnings and cautions	Warnings and cautions when using medical equipment, including preventive measures for protecting the patient from hazards of using the medical equipment; this may be warnings about the risks or bad effects of misuse of such equipment and preventive measures
1.7	Possible bad effects	Information about bad effects related to the use of medical equipment which is recorded via clinical testing and post-marketing supervision of such medical equipment
2	Information about products sold in various countries (if any)	
	Information about countries which have approved the sale of products and about the first country granting registration/approving the sale of medical equipment	
3	Instruction which has been registered in other countries (if any) List of countries which have granted registration of sale, enclosed with the instruction which has been approved in such country; date of issue of registration	
4	Information about the noticeable safety/operation of medical equipment products - Information about quantity of reports on bad effects related to the use of medical equipment; Measures of recall/ post-marketing adjustment which have been carried out at the request of regulatory bodies of various countries; - If the medical equipment contains any of the following component, these information shall be additionally provided: Cell, animal or human tissue or their derivatives used as not alive - for example artificial heart valve	

	from pig, catgut…; Cells, tissues and or derivatives from micro-organisms or recombinant - eg skin inflation products based on hyaluronic acid obtained from bacterial fermentation process ...; There are irritant or ionized ingredients - eg X-ray; or non-ionizing - ag laser, ultrasound ...

We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

Form No. 02

TECHNICAL DOCUMENTS FOR REAGENTS, CALIBRATION SOLUTIONS, IN-VITRO CONTROL MATERIALS

Name and address of the establishment applying for the registration number of the medical equipment

.....[Date].....

No.	Heading	Content
I	**General information about medical equipment**	
1.1	General description	Introduction of medical equipment, purposes, products for use in combination (if any)
1.2	History of marketing of the product	Name of the first country to be licensed and year of licensing
1.3	Use purpose	Use purposes/ instructions which are planned to be displayed on the label or the instruction sheet
1.4	List of countries obtaining the permit	List of countries which have obtained the permits and the years of licensing
1.5	Conditions of applications which have been submitted but have not obtained the permits	List of countries which have submitted the applications but have not obtained the permits
1.6	Important information related to the safety and effectiveness of the products	Summary of reports on bad effects and remedial measures taken since the products are sold
II	**Description of medical equipment**	
2.1	Description of medical equipment	Description of operating principle and technical features and parameters of the medical equipment
2.2	Instruction	Summary of instruction to use the equipment accoridng to the Instruction sheet or the Information sheet of the medical equipment

2.3	Contraindications	Information about cases where the equipment must not be used so as for the safety of the patient, e.g. due to anamnesis or physiological features of the patient, etc.; in accordance with the contents displayed on the label of the equipment
2.4	Warnings and cautions	Warnings and cautions when using medical equipment, including preventive measures for protecting the patient from hazards of using the medical equipment; this may be warnings about the risks or hazards of misuse of such equipment and preventive measures
2.5	Possible bad effects	Information about bad effects related to the use of medical equipment which is recorded via clinical testing and post-marketing supervision of such medical equipment
2.6	Alternative measures (if any)	Other measures to reach the same goals
2.7	Information about raw materials	List of raw materials of products and description about them
2.8	Relevant technical parameters	Characteristics about the efficiency and technical parameters including: detection limit, trueness and precision, sensitivity, specificity, reliability and other factors; other technical parameters including chemical, physical, biological factors, sterilization, stability (useful life), preservation, transport, packaging.
III	**Production of medical equipment**	
3.1	Manufacturer	Name of manufacturers involving in the manufacture and the applicable quality control system
3.2	Information about the safety of the product	Safety note. If the product has biological components, the manufacturer shall make a list of such biological components (derivated from human or animals) and undertake/declare having conducted inspection of such factors according to the standards prescribed by the company.
3.3	Manufacturing process	General plans on manufacture and control of product quality. Note of inspection of finished products.
3.4	Stability	Objectives, results and conclusion about the stability of the product
IV	**Research reports**	
4.1	Pre-clinical researches	Objectives, methods, results and conclusion about the pre-clinical researches
4.2	Clinical researches and clinical evidences (if any)	Objectives, methods, results and conclusion about the clinical researches
4.3	References	List of references

We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

ANNEX IX

TABLE OF DATA ON CLINICAL TEST OF MEDICAL EQUIPMENT
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the establishment applying for registration of sale of medical equipment: .....[1].....

.....[Date].....

DATA ON CLINICAL TEST OF MEDICAL EQUIPMENT

No.	Heading	Content
1	Name of medical equipment	
2	Model	
3	Technology used for the equipment	
4	Component materials	
5	Clinical instruction and application	
6	Use purposes	
7	Instructions about use effects	
8	Expected useful life of the equipment	
9	Warnings and cautions for use of the equipment during the conduct of treatment	
10	Analysis and assessment of level of risks/usefulness of the equipment	
11	Evaluation of potential risks of the equipment	
12	Evaluations of cultural, geographic and demographic factors (e.g. ages, nations, genders, etc.)	
13	Similar usings of the equipment upon the same safety standards, taking into account moral factors	
14	Relevant evidences and clinical evaluation	
15	Information about the manufacture of the equipment: information about the manufacturing process, manufacturing conditions, means used for the manufacture, packaging, labeling, storage, preservation	

	and transport.	

We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Name and address of the establishment

ANNEX X

REPORT ON SALE OF MEDICAL EQUIPMENT
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Holder of the registration number

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

REPORT ON SALE OF MEDICAL EQUIPMENT

To: The Ministry of Health (Department of Medical Equipment and Works).

Name of the holder of the registration number: .....

Tax codes or Number of the representative office establishment license: .....

Address: .....

Phone number: ..... Fax: .....

Name of the lawful representative of the establishment: .....

Phone number: ..... Phone number (mobile): .....

.... I - the holder of the registration number..... - hereby present the sale of medical equipment during the effect of the registration number as follows:

No.	Name of medical equipment	Model	Quantity	Manufacturer, Country of manufacture	Owner	Year of manufacturer	Registration number
1							
2							
...	...						

Other contents:

1. Errors occuring during the sale of the medical equipment:

2. Changes during the sale:

We - the establishment selling medical equipment - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

---

[1] Location

ANNEX XI

COMMITMENT TO PROVIDING THE WARRANTY AND MAINTENANCE AND PROVIDING MATERIALS SERVING THE USE OF MEDICAL EQUIPMENT
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name of establishment

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: .....

.....[1]....., ...[Date].....

COMMITMENT

To: The Ministry of Health (Department of Medical Equipment and Works)

Name: .....

Tax codes: .....

Address: .....

Lawful representative: .....

Contact number: ..... :

We - .....[2]..... - are conducting the distribution of the following medical equipment:

Name of the medical equipment: .....

Registration number: ..... Date of issue: .....

.....[3]..... cannot continue operating but we are still capable of quality assurance of such medical equipment, we, therefore, hereby commit to:

- Taking responsibility for ensuring the quality, model, quantity of imported medical equipment issued with the registration number.

- Selling medical equipment for not exceeding 24 months.

- Taking responsibility for providing warranty and maintenance of medical equipment.

- Providing materials and substitute fittings for 8 năm during the use of the equipment.

- Fulfilling requirements for technicians and ensuring the effectiveness and the safety of medical equipment towards the operators and the environment, ensuring the unchanging of quality of the imported equipment in conditions pertaining to facilities, transport vehicles. Ensuring the fulfillment of requirements for labels of medical equipment.

- Ensuring the the proper use of medical equipment. Facilitating the inspection of competent authorities.

We will take all legal responsibility for any violation we commit against these above provisions.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location
2. Name of the distributing establishment
3. Nam of the owner of the medical equipment